## **Orchid Island Juice Company**



330 North U.S. Highway 1 Fort Pierce, Florida 34950-4297 Phone (561) 465-1122 Fax (561) 465-4303



November 22, 2000

Food and Drug Administration 5630 Fishers Lane Room 1061 Rockville, MD 20852

ATTENTION:

**Management Branch** 

**HFA - 305** 

RE:

Docket #00N1351

To Whom It May Concern:

Orchid Island Juice Company has already commented on its position on the question brought forth by the Food and Drug Administration on the definition of the word "fresh". An additional piece of information I think you should be very interested in, is the Florida rule recently passed at the Florida Department of Citrus meeting by a margin of eleven to one votes, which specifically addresses the definition of the word "fresh". Please take note on Page 1 - Paragraph (1) goes on to say:

(1) Fresh – The term "fresh", when used on the label or in labeling of a food in a manner that suggests the food is unprocessed, means the food is in its raw state and has not been frozen or subjected to any form of thermal processing or any other form of preservation.

To further define the word on Page 2 - Rule 2049.003 goes on to define fresh squeezed citrus juices as:

20-49.03.1 Fresh Squeezed Citrus Juices.

The provisions of this section shall apply to all fresh citrus juices that have not been frozen or treated to reduce the enzymatic activity and the number of viable microorganisms.

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I think that this ruling is very important since the leaders of the citrus industry of the United States of America have gone to great lengths to clear up any misunderstanding of the definition of the word "fresh".

We at Orchid Island Juice Company concur whole heartedly with the Department of Citrus and the Department of Agriculture in the State of Florida with this definition. I might add that the Florida Department of Agriculture completely supports this entire proposal.

If you have any questions, please contact me.

Sincerely,

John Martinelli

President

JM/sb

Encl. - Draft A(7) - Proposed New Rule to Department of Citrus Rules

CC:

Ms. G.A. June

**FDA** 

200 C Street, SW

Washington, DC 20204

1	DRAFT A(7)	
2		PROPOSED NEW RULE TO
3		DEPARTMENT OF CITRUS RULES
4		CHAPTER 20-49
5		STANDARDS FOR FRESH SQUEEZED CITRUS JUICES
6	20-49.001	Purpose.
7	20-49.002	Definitions.
8	20-49.003	Fresh Squeezed Citrus Juices.
9	20-49.004	Wholesale Producers - Testing.
10	20-49.005	Wholesale Producers - Inspections.
11	20-49.006	Small Producers - Testing.
12	20-49.007	Small Producers - Inspections.
13	20-49.008	Retail Grocery Producers - Testing and Inspections.
14	20-49.009	Fresh Squeezed Orange Juice Marked with Florida Citrus Growers' Certification Mark.
15	20-49.010	Fresh Squeezed Grapefruit Juice Marked with Florida Citrus Growers' Certification Mark.
16		
17	20-49.001	Purpose.
18	The purpose of this section is to regulate all fresh squeezed citrus juices.	
19	Specific Authority 601.10(7), 601.11 FS.	
20	Law Implemented 601.10(7), 601.11, 601.48 FS.	
21	History – New	
22		
23	20-49.002	Definitions.
24	(1)	Fresh -The term fresh, when used on the label or in labeling of a food in a manner that
25	suggests the food is unprocessed, means the food is in its raw state and has not been frozen or subjected	
26	to any form of thermal processing or any other form of preservation. At all times this definition and its	
27	application to fresh citrus juice must be consistent with the definition established by the Food and Drug	
28	Administration, 21 CFR 101.95, revised April 1, 2000, incorporated herein by reference.	
	CODE: New language is designated by a s <u>ingle underline.</u> Struck through type designates deletions from existing rule.	

- (2) Wholesale Producer A Wholesale Producer includes all Florida producers of fresh squeezed citrus juices, that each season process juice from 30,000 boxes or more of citrus fruit.
- (3) Small Producer Gift Fruit Shippers as defined in 601.03(20), Florida Statutes, and roadside retail fruit stand operators, as defined in 20-44.006, F.A.C., engaged in the production of fresh squeezed citrus juices and process less than 30,000 boxes of citrus fruit per season. All producers in the category shall possess a food permit issued by the Florida Department of Agriculture and Consumer Services (hereafter "FDACS") pursuant to the provisions of 5K-4, F.A.C.
- (4) Retail Grocery Producer -- Retail grocery producers, as defined in section 20-44.006, F.A.C., who produce fresh citrus juices on its premises and sell one hundred percent (100%) of said fresh squeezed citrus juices directly to the consumer. All producers in this category shall possess a food permit issued by FDACS pursuant to the provisions of 5K-4, F.A.C.
- (5) Product -- The term Product shall mean fresh squeezed citrus juices. The words "fresh squeezed" or "freshly squeezed or "fresh" may be used to describe product conforming to this rule.
- (6) Establishment The term establishment shall reference the Wholesale Producer, Small Producer and Retail Grocer's facility and/or place of business.

Specific Authority 601.10(7), 601.11 FS.

Law Implemented 601.10(7), 601.11, 601.48 FS.

History – New \_\_\_\_\_.

20-49.003 Fresh Squeezed Citrus Juices.

The provisions of this section shall apply to all fresh citrus juices that have not been frozen or treated to reduce the enzymatic activity and the number of viable microorganisms.

- (1) Product shall only be made from the unfermented juice of mature citrus fruit.
- (2) The Product shall not contain soluble solids recovered by aqueous extraction of washing of fruit pulp.
  - (3) Addition of a sweetening ingredient or any other additive to the Product is not permitted.
- (4) The producers' Product and producers' establishment shall be subject to regular inspection by the FDACS or its agents.

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- (5) Product that is packaged into a retail container must be bottled in the same establishment in which it was extracted and shall remain under the control of one single producer. Under no circumstances shall Product be transported in bulk containers or tankers to be bottled at another location.
- (6) The package or container shall be legibly labeled with the maximum shelf life during which such product may be offered for sale, and such date shall not exceed 17 days from the time of extraction. This provision shall not apply to product packed by any person who packs for retail sale directly to consumer, not for resale.
- (7) Upon meeting juice content requirements prior to August 1, fruit designated for the purpose of cold storage and used in the production of fresh citrus juice shall not be subject to retesting for juice content at the time of removal from cold storage.

Specific Authority 601.10(7), 601.11 FS.

Law Implemented 601.10(7), 601.11, 601.48 FS.

History - New \_\_\_\_\_

20-49.004 Wholesale Producers - Testing.

This section regarding testing shall be applicable to Wholesale Producers of fresh citrus juice.

- (1) All Wholesale Producers must document compliance with all applicable state and federal food safety and labeling requirements.
- (2) All Wholesale Producers must have, maintain and follow a food safety plan that is based on Hazard Analysis Critical Control Point (HACCP) principles. This plan must be reviewed by Fiorida Department of Agriculture and Consumer Services (hereafter "FDACS"), the applicable regulatory agency or a firm accredited by the International HACCP Alliance. Such plan shall incorporate a microbiological testing program. Such documentation must be on file at each producer's facility. These plans must be reviewed every 12 months or each time an operational modification changes the producing establishment's hazard analysis.
- (3) All Wholesale Producers must abide by all applicable Good Manufacturing Practices contained in 5K-4, F.A.C. and 21 CFR 110, revised April 1, 2000, and incorporated herein by reference.
- (4) All Wholesale Producers must test for Salmonella, E.coli\_and other pathogenic

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microorganisms as required by applicable regulatory agencies. Microbiological results must be available for each production lot or day's production, whichever is less. Microbiological testing records must be maintained on the producing establishment's premises for one year, and shall be available for review by FDACS or United States Department of Agriculture (hereafter "USDA") during normal operating hours.

(5) Any positive detection of *Salmonella*, *E.coli* or other pathogenic microorganisms in a wholesale operation shall require notification to USDA and FDACS. Division of Food Safety, within 24 hours of the positive detection. If Product is still located in the producing establishment, it shall be placed on hold pending appropriate response from FDACS.

Specific Authority 601.10(7), 601.11 FS.

Law implemented 601.10(7), 601.11, 601.48 FS.

History – New \_\_\_\_\_

20-49.005 Wholesale Producers - Inspections.

This section regarding the inspections shall be applicable to Wholesale Producers of fresh squeezed citrus juices.

- (1) All inspections and audits shall be performed by or under the authority of FDACS.
- (2) All wholesale production establishments shall be inspected according to sections 2.2.1 through 2.2.58, July 1996, and 3.2.7a 3.2.7o, June 1996, of the Citrus Handbook of the Processed Citrus Branch, Fruit and Vegetable Division, United States Department of Agriculture, incorporated herein by reference.
  - (3) All Wholesale Producers shall be subject to full-time inspection by FDACS or its agent.
- (4) The following specific Good Manufacturing Practices, in addition to those contained in 5K-4, F.A.C., and 21 CFR 110, revised April 1, 2000, incorporated herein by reference, shall be applicable:
  - (a) All soil, debris, stems, leaves, etc. must be removed from the fruit.
- (b) All whole and intact fruit shall be washed, sanitized and/or surface heat-treated immediately prior to extraction.
- (c) All fruit that has been in cold storage shall be resanitized and regraded. All soft or CODE: New language is designated by a single underline. Struck through type designates deletions from existing rule.

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## ALICE P. WIGGINS License & Permit Administrator Legal Department

FLORIDA DEPARTMENT OF CITRUS 1115 EAST MEMORIAL BOULEVARD P. O. BOX 148 LAKELAND, FL 33802-0148

TELEPHONE: (863) 499-2519 FAX: (863) 284-4315 E-Mail awiggins@citrus.state.fl.us

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